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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,500	08/01/2001	Nobuhiko Ogura	Q65512	3311
7590 02/16/2006 SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC 2100 Pennsylvania Avenue, N.W. Washington, DC 20037-3202			EXAMINER	
			RILEY, JEZIA	
			ART UNIT	PAPER NUMBER
washington, D	C 20037-3202	751 5202	1637	
			DATE MAILED: 02/16/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
ੇ <b>,</b>			OGURA, NOBUHIKO			
Office Action Summary		09/918,500	Art Unit			
		Examiner				
	The MAILING DATE of this communication app	Jezia Riley ears on the cover sheet with the c	1637 orrespondence address			
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠	Responsive to communication(s) filed on 30 Ja	nuary 2006.				
	· <del></del>	action is non-final.				
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4) Claim(s) See Continuation Sheet is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 3, 66-75, 79, 82, 85, 88-89, 92, 95, 98, 101, 104, 107, 110, 113, 116, 119, 122, 125, 128, 131, 134, 137, 140-146, 149, 152, 155, 158, 161, 164, 167, 170-184 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.  Application Papers  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2) Notice 3) Information	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa				

Continuation of Disposition of Claims: Claims pending in the application are 3,66-75,79,82,85,88,89,92,95,98,101,104,107,110,113,116,119,122,125,128,131,134,137,140-146,149,152,155,158,161,164,167 and 170-184.

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#### **DETAILED ACTION**

### Response to Remarks

Applicants' arguments, filed on 1/30/06, have been approved and entered. They have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 66-75, 79, 82, 85, 88-89, 92, 95, 98, 101, 104, 107, 110, 113, 116, 119, 122, 125, 128, 131, 134, 137, 140-146, 149, 152, 155, 158, 161, 164, 167, 170-184 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 3, 89, 142, 172, 175, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed

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(those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claims 3, 66-75, 79, 82, 85, 88-89, 92, 95, 98, 101, 104, 107, 110, 113, 116, 119, 122, 125, 128, 131, 134, 137, 140-146, 149, 152, 155, 158, 161, 164, 167, 170-184 are vague and indefinite because of the term "capable of". It is unclear whether the material actually do attenuate radiation energy, because having the capability is not the same thing as actually performing the function. A positive recitation is required. Same problem for "capable of forming a membrane filter" and capable of generating chemiluminescent emission".

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3, 70-75, 79, 82, 85, 88, 89, 92, 95, 98, 113, 116, 119, 122, 125, 128, 131, 134,174-178, 182-184 rejected under 35 U.S.C. 102(e) as being anticipated by Wohlstadter et al. (US 6,207,369 B1).

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Wohlstadter et al teach a general method and apparatus for performing a binding assay for an analyte of interest in a sample based upon measurement of electrochemiluminescence at an electrode surface. Wohlstadter et al teach that assays based on the measurement of electro- chemiluminescence comprise capturing the analyte of interest on a coated solid phase surface wherein said surface is coated with a binding agent or multiple binding reagents having the same or different binding affinity, such as e.g., antibodies or enzymes, and etc. and; incubating the compositions to form a complex and inducing luminescence on the complex by imposing voltage on said electrode and measuring the emitted luminescence at the electrode surface to measure the presence of the analyte of interest in the sample, wherein said analyte may comprise an amino acid sequence (peptide or protein or fragment thereof), an enzyme, enzyme substrate, nucleic acid, kinase or etc (col. 51, lines 8-60, see also abstract, col. 6, line 63 to col. 7, line 45; col. 11, line 60 to col. 14, line 40; col. 24, line 15 to col. 25, lines 61; col. 47, lines 6-19). Wohlstadter et al teach wherein the apparatus for carrying out the assay may be multi-arrayed (col. 31, section 5.7) or multi-well plate comprising 24, 96 or 384 wells (col. 68, lines 13-60). The substrate may be solid, or if filtration of samples through the electrode or wicking of samples along the electrode is desired, the substrate may be a porous material e.g., a filtration membrane (col.15). By way of example, the supporting material may be a metal, plastic, polymer, elastomer, gel, paper, ceramic, glass, liquid, wax, oil, paraffin, organic solid, carbon or a mixture of two or more of each. The material may be solid or liquid. If it is solid, it may contain one or a plurality of holes or pores. In specific examples, the support may be a metal mesh, a nylon filter membrane or a filter paper. (col.35).

Modifications required include the provision for support handling which is viewed as that inherently the support need to comprise a gripping portion in order for it being gripped. (col. 44, lines 45-46, col. 46, lines 22-23)

The porous material may be combined with additional materials or sandwiched between two matrails (col.17) which is viewed as being inclusive of instant claim 92.

The use of wells, deposition of reaction medium or sample on felts or porous materials, deposition and drying of reaction medium or sample on gels, films, etc., can be used to inhibit spreading or diffusion. Each of such discrete domains is less than 1 mm in diameter or width, preferably in the range of 50 nm to 1 mm, most preferably in the range of 1 micron to 1 mm. The same or different reaction medium can be deposited on each of the discrete domains prior to sample application, or sample application can precede deposition of reaction medium. (col.56-57, bridging paragraph).

Wohlstadter et al teach that the detection method and apparatus is useful because it can be tailored to control performance, cost and manufacturability to make amenable to use in a disposable format (col. 6, lines 60-62 and because it provides the end user with immobilized binding reagents for one or more analyte (col. 68, lines 49-50) thus being useful in high throughput screening assays (col 57, lines 65-67).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Wednesday, February 15, 2006

Jezia Riley

Primary Examiner